Comparison of INTRAGAM® P, KIOVIG 10%, OCTAGAM® 5% and OCTAGAM® 10%

DESCRIPTION	INTRAGAM® P	KIOVIG 10%	OCTAGAM® 5%	OCTAGAM® 10%
Presentation	Solution; 3g (50mL) or 12g (200mL) vials	Solution; 1g (10mL), 2.5g (25mL), 5g (50mL), 10g (100mL), 20g (200mL) vials	Solution; 1g (20mL), 2.5g (50mL), 5g (100mL), 10g (200mL) vials	Solution; 2g (20mL), 5g (50mL), 10g (100mL), 20g (200mL) vials
Concentration	6%	10%	5%	10%
Source Plasma	Australian volunteer non-renumerated donors	European and USA remunerated and non-remunerated Qualified Only donors (QSEAL certified)	European and USA remunerated and non-remunerated donors	European and USA remunerated and non-remunerated donors
Plasma Testing	Hepatitis B surface antigen; antibodies to HIV 1/2, hepatitis C and HTLV-I/II; nucleic acid testing for hepatitis B, hepatitis C and HIV-1	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C: nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis B, hepatitis C and HIV-1	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis B, hepatitis C and HIV-1
Manufacturer	CSL Limited, Biotherapies Division, Broadmeadows, Australia	Baxter AG Industriestasse 67, A-1221, Vienna, Austria	Octapharma Produktionsges.m.b.H., Vienna, Austria Octapharma Lingolsheim, France	Octapharma Produktionsges.m.b.H., Vienna, Austria Octapharma Lingolsheim, France
Distributor	Australian Red Cross Blood Service	Baxter Healthcare Pty Ltd Australian Red Cross Blood Service	Octapharma Australia Pty Ltd, Australian Red Cross Blood Service	Octapharma Australia Pty Ltd, Australian Red Cross Blood Service
Manufacturing Process	Chromatographic fractionation	Cold ethanol fractionation, ion exchange chromatography, ultrafiltration	Cold ethanol fractionation	Cold ethanol fractionation
Viral Safety	Two dedicated steps: • Pasteurisation (60°C for 10 hours) • Incubation at low pH	Three dedicated steps: • Solvent/Detergent (S/D) treatment • 35 nm nanofiltration • Incubation at low pH (pH4.4-4.9) and elevated temperature (30-32°C) for 21-22 days	Two dedicated steps: • Solvent/Detergent (S/D) treatment • Incubation at low pH (pH4)	Two dedicated steps: • Solvent/Detergent (S/D) treatment • Incubation at low pH (pH4)
Stabiliser [1]	Maltose[2]	Glycine	Maltose[2]	Maltose[2]
Storage Conditions	Refrigerate at 2-8°C for up to 2 years. Once removed from refrigeration, store below 25°C and use within 3 months	Refrigerate at 2-8°C for up to 3 years. May be stored at room temperature (below 25°C) for up to 12 months within the first 24 months. However, once stored at room temperature, the product must remain stored at room temperature and must be used within the first 24 months from the date of manufacture.	Store below 25°C for up to 2 years	Refrigerate at 2-8°C for up to 2 years. Once removed from refrigeration, store below 25°C and use within 3 months
Need for Reconstitution	No	No	No	No

DESCRIPTION	INTRAGAM® P	KIOVIG 10%	OCTAGAM® 5%	OCTAGAM® 10%
Dosage and Administration	For intravenous use only, see approved Product Information for rate of infusion			
Relative IgG subclass content	IgG1 61% IgG2 36% IgG3 3% IgG4 1%	IgG1 ≥ 56.9% IgG2 ≥ 26.6 % IgG3 ≥ 3.4% IgG4 ≥ 1.7%	IgG1 ca. 65% IgG2 ca. 29% IgG3 ca. 4% IgG4 ca. 2%	IgG1 ca. 60% IgG2 ca. 32% IgG3 ca. 7% IgG4 ca. 1%
IgA level [3]	< 0.025mg/mL	Average 0.03mg/mL Max < or equal to 0.14mg/mL	< or equal to 0.2mg/mL	< or equal to 0.4mg/mL
Precautions and Adverse Reactions [4]	See approved Product Information. Note that different IVIg products have different infusion rates and some adverse reactions may be infusion rate dependent			

The information contained in the above table has been provided and approved by CSL Biotherapies, Baxter and Octapharma.
The Australian Red Cross Blood Service makes no warranties in relation to the products, KIOVIG 10%, OCTAGAM® 5% and OCTAGAM® 10%, nor the information provided about these products.

Notes:

1. Although the majority of renal adverse events have occurred with sucrose containing IVIg products, caution is advised during administration of any IVIg product.
2. The maltose present in INTRAGAM P, OCTAGAM® 5% and OCTAGAM® 10% may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment, hypoglycaemia may occur. (Reference: INTRAGAM P, OCTAGAM® 5% and OCTAGAM® 10% Product Information).
3. In IgA deficient patients, product with the lowest IgA level should be selected.
4. Infusion of IVIg may lead to a relative increase in blood viscosity. Patients should be adequately hydrated prior to commencement of the infusion. IVIg should NOT be infused rapidly to patients at increased risk of thromboembolic and renal adverse events, particularly when using higher concentration IVIg products.